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ABSTRACT

This document presents the international rules for precollege science research. Sections include: (1) Quick Rules Reference; (2) Highlights for 1995-96; (3) International Science and Engineering Fair (ISEF) Category Descriptions; (4) Display and Safety Regulations; (5) Eligibility; (6) Requirements; (7) Limitations; (8) Continuation of Projects; (9) Team Projects; (10) Who Is Involved in a Science Project?; (11) Human Subjects; (12) Nonhuman Vertebrate Animals; (13) Pathogenic Agents; (14) Controlled Substances; (15) Recombinant DNA; (16) Human and Animal Tissue; and (17) Forms. (JRH)

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INTERNATIONAL RULES FOR PRECOLLEGE SCIENCE RESEARCH: GUIDELINES FOR SCIENCE FAIRS

JUNE 1995- MAY 1996

ERRATA

International Rules for Precollege Science Research:
Guidelines for Science Fairs,
page 28, Form 1B, #2...

...reads: 2) Required for those projects that need prior approval (i.e., see Item #**10** on Form 1A.)

...should read: 2) Required for those projects that need prior approval (i.e., see Item #**9** on Form 1A.)

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Acknowledgment

Teachers, scientists, parents, and adult volunteers inspire and encourage students to explore and investigate their world through hands-on research. Those of you who work with these young people are rarely recognized and never can be adequately thanked. Without you, science projects and science fairs would not be possible.

Science Service applauds your commitment and appreciates your hard work. We sincerely hope that our efforts to enhance the Rules will serve you in working with students.

Dr. Alfred S. McLaren
President, Science Service Inc.

Dr. Virginia Rhodes
ISEF SRC Chairperson

The International Science and Engineering Fair Scientific Review Committee (ISEF SRC) and Science Service will be glad to answer any questions or concerns about the *International Rules for Precollege Science Research: Guidelines for Science Fairs*.

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Quick Rules Reference

(The following is a partial list of rules and is not meant to replace the contents of this booklet. It will help to identify and locate specific rules in this booklet. Page numbers are identified).

ALL PROJECTS

- All students must meet with sponsor and complete checklist before beginning experimentation ⇨ 26
- Any proposed changes in the research plan after initial IRB and/or SRC approval must have subsequent IRB and/or SRC approval before experimentation begins/resumes ⇨ 7
- All studies involving acceptable risk in human subjects, nonhuman vertebrate animals, pathogenic agents, controlled substances, non-excempt recombinant DNA and certain tissue studies must have a Qualified Scientist ⇨ 11,14,17,18,19,21
- Adult Sponsor and Qualified Scientist cannot serve on an IRB/SRC reviewing their student's project ⇨ 9
- The use of hazardous chemicals and equipment, firearms, radioactive substances and radiation require review and proper supervision by a Designated Supervisor ⇨ 26

HUMAN SUBJECTS

- Research must be reviewed and approved by an IRB before experimentation begins ⇨ 10
- Informed consent recommended for all projects using human subjects and required for projects in which acceptable risk is determined by the IRB ⇨11

RECOMBINANT DNA

- Non-exemt rDNA studies must be conducted in a federally registered research institution under the direct supervision of a Qualified Scientist ⇨ 19
- Exempt rDNA studies may be conducted in a nonfederally registered laboratory (including school laboratory) under direct supervision of trained teacher or Qualified Scientist ⇨ 19

CONTROLLED SUBSTANCES

- Students must adhere to all federal regulations governing controlled substances ⇨ 18
- Students under 21 may not purchase/or handle smokeless powder or black powder ⇨ 18,

NONHUMAN VERTEBRATE ANIMALS

- Alternatives to the use of vertebrate animals for research must be explored ⇨ 12, 15
- All animals must be legally acquired from reputable animal breeders ⇨ 12
- Experiments involving laboratory animals cannot be conducted in a student's home; exceptions can be made for behavioral studies by the governing SRC ⇨ 12, 13
- Proper animal care must be provided daily including weekends and vacations ⇨ 13
- Experimental procedures that cause unnecessary pain or discomfort are prohibited ⇨ 13
- Experiments designed to kill vertebrate animals are not permitted ⇨ 13
- Students may not perform euthanasia, except in emergency situations ⇨ 13
- LD_{50} or higher in any group or subgroup is not permitted ⇨ 13
- Acid rain, insecticide, herbicide, and heavy metal toxicity studies are prohibited ⇨ 13

HUMAN AND ANIMAL TISSUE

- Human blood (and products) must be documented free of HIV and hepatitis viruses and/or must be handled by acceptable containment procedures applicable to blood borne pathogens. ⇨ 21
- Students using their own blood do not need HIV or hepatitis certifications ⇨ 21
- For the purposes of student research all body fluids, including saliva and urine, are to be considered tissues ⇨ 21

PATHOGENIC AGENTS

- Organisms collected, isolated, and/or cultured from any environment should be considered potentially pathogenic ⇨ 17

Highlights for 1995-1996

Rule Changes

- ✓ Because of federal regulations requiring local community involvement, an IRB should be established at the school level to deal with human research projects. If it is impossible to establish an IRB at each local school, the teacher/school should contact the regional fair director for assistance in evaluating human research prior to experimentation.
- ✓ Written informed consent is recommended for all human research subjects and required for projects in which acceptable risks are determined by the IRB.
- ✓ Important restrictions for rDNA studies: (1) recombinants containing DNA coding for oncogenes or other human, plant, or animal toxins (including viruses) cannot be made and/or propagated; (2) students must not use ethidium bromide or handle gels stained with ethidium bromide.
- ✓ Exempt rDNA studies may be supervised by a trained teacher or a Qualified Scientist.
- ✓ Certain tissue studies may require a Qualified Scientist.
- ✓ Studies involving hazardous substances or devices require a Designated Supervisor.
- ✓ The use of firearms in research projects requires a Designated Supervisor.

Important Notes

- ✓ Form (1C) is required for all studies conducted in an institutional or industrial setting during the current ISEF year.
- ✓ A team project cannot be converted into an individual project. A new member may not be added to a continuing team project, but two original team members may continue their research if the third member no longer participates.
- ✓ Students should retain signed copies of all forms. (These may be originals or copies.) When a student sends (1A) Research Plan and (1B) Approval Form to the regional/state fair for approval, the region/state should return a signed copy to the student. Do not send original forms to any fair, including the ISEF.
- ✓ Display of photographs or other visual images, including videotapes, of human subjects from a study is permitted as long as the student researcher obtains informed consent from the subject(s).
- ✓ A death rate of 50 percent or greater in any group of vertebrates is not permitted. This rule also applies to subgroups.

These Rules also apply to

The 47th International Science and Engineering Fair (ISEF)

Tucson, Arizona
May 5 - 11, 1996

ISEF Category Descriptions

1) **Behavioral and Social Sciences**
Human and animal behavior, social and community relationships--psychology, sociology, anthropology, archaeology, ethology, ethnology, linguistics, learning, perception, urban problems, reading problems, public opinion surveys, educational testing, etc.

2) **Biochemistry**
Chemistry of life processes--molecular biology, molecular genetics, enzymes, photosynthesis, blood chemistry, protein chemistry, food chemistry, hormones, etc.

3) **Botany**
Study of plant life--agriculture, agronomy, horticulture, forestry, plant taxonomy, plant physiology, plant pathology, plant genetics, hydroponics, algae, etc.

4) **Chemistry**
Study of nature and composition of matter and laws governing it--physical chemistry, organic chemistry (other than biochemistry), inorganic chemistry, materials, plastics, fuels, pesticides, metallurgy, soil chemistry, etc.

5) **Computer Science**
Study and development of computer software and hardware and associated logical devices.

6) **Earth and Space Sciences**
Geology, mineralogy, physiography, oceanography, meteorology, climatology, astronomy, geology, speleology, seismology, geography, etc.

7) **Engineering**
Technology; projects that directly apply scientific principles to manufacturing and practical uses--civil, mechanical, aeronautical, chemical, electrical, photographic, sound, automotive, marine, heating and refrigerating, transportation, environmental engineering, etc.

8) **Environmental Sciences**
Study of pollution (air, water, and land) sources and their control; ecology.

9) **Mathematics**
Development of formal logical systems or various numerical and algebraic computations, and the application of these principles--calculus, geometry, abstract algebra, number theory, statistics, complex analysis, probability.

10) **Medicine and Health**
Study of diseases and health of humans and animals--dentistry, pharmacology, pathology, ophthalmology, nutrition, sanitation, pediatrics, dermatology, allergies, speech and hearing, etc.

11) **Microbiology**
Biology of microorganisms--bacteriology, virology, protozoology, fungi, bacterial genetics, yeast, etc.

12) **Physics**
Theories, principles, and laws governing energy and the effect of energy on matter--solid state, optics, acoustics, particle, nuclear, atomic, plasma, superconductivity, fluid and gas dynamics, thermodynamics, semiconductors, magnetism, quantum mechanics, biophysics, etc.

13) **Zoology**
Study of animals--animal genetics, ornithology, ichthyology, herpetology, entomology, animal ecology, paleontology, cellular physiology, circadian rhythms, animal husbandry, cytology, histology, animal physiology, invertebrate neurophysiology, studies of invertebrates, etc.

14) **Team Projects**
All disciplines--multidisciplinary or interdisciplinary.

Display and Safety Regulations

Unacceptable for Display

1) living organisms (*e.g.*, plants, animals, microbes)
2) dried plant materials
3) taxidermy specimens or parts
4) preserved vertebrate or invertebrate animals (includes embryos)
5) human or animal food
6) human/animal parts (**Exceptions**: teeth, hair, nails, dried animal bones, histological dry mount sections, and wet mount tissue slides)
7) soil or waste samples
8) chemicals including water
9) poisons, drugs, controlled substances, hazardous substances or devices (*i.e.*, firearms, weapons, ammunition, reloading devices)
10) dry ice or other sublimating solids (*i.e.*, solids which vaporize to a gas without passing through a liquid phase)
11) sharp items (*i.e.*, syringes, needles, pipettes)
12) flames or highly flammable display materials
13) empty tanks that previously contained combustible liquids or gases, **UNLESS** purged with carbon dioxide
14) batteries with open top cells
15) awards, medals, business cards, flags, etc.
16) hand-outs to judges must be limited to one page narratives related to the essentials of this year's project. Personal photographs, accomplishments, acknowledgements, addresses, and phone and fax numbers are not permitted
17) photographs or other visual presentations depicting vertebrate animals in other-than-normal conditions (*i.e.*, surgical techniques, dissection, necropsies or other lab techniques)

Acceptable for Display Only *(cannot be operated)*

1) projects with unshielded belts, pulleys, chains, and moving parts with tension or pinch points
2) class III and IV lasers
3) any device requiring voltage over 110 volts

Acceptable for Display & Operation *(with restrictions)*

1) Class II lasers:
   a) must be student-operated
   b) posted sign must read "Laser Radiation: Do Not Stare Into Beam"
   c) must have protective housing that prevents access to beam
   d) must be disconnected when not operating
2) Large vacuum tubes or dangerous ray-generating devices must be properly shielded.
3) Pressurized tanks that contained noncombustibles may be allowed if properly secured.
4) Any apparatus producing temperatures that will cause physical burns must be adequately insulated.
5) High-voltage equipment must be shielded with a grounded metal box or cage to prevent accidental contact.
6) High-voltage wiring, switches, and metal parts must have adequate insulation and overload safety factors, and must be inaccessible to others.
7) Electric circuits for 110-volt AC must have a nine-foot (min.) cord. The cord must have sufficient load-carrying capacity and be approved by Underwriters Laboratories.
8) Electrical connections in 110-volt circuits must be soldered or made with approval connectors. Connecting wires must be insulated. Voltage greater than 110 volts is not permitted.
9) Bare wire and exposed knife switches may be used only in circuits of 12 volts or less; otherwise, standard enclosed switches are required.

Size of Display at the ISEF

76 cm (30 in) deep
122 cm (48 in) wide
274 cm (108 in) high *including table*

NOTE: *Backboards are not provided at the ISEF. Display area consists of a draped table and a curtained back.*

Eligibility

Each ISEF affiliated fair may send up to two Finalists and one team project to the ISEF. Any student in grades 9-12 or equivalent is eligible, none of whom has reached age 21 on or before May 1 preceding the ISEF.

Requirements

1) Every student must complete (1A) Research Plan and (1B) Approval Form.
2) Certain projects require additional forms. Experiments that involve human subjects, non-human vertebrate animals, pathogenic agents, controlled substances, recombinant DNA, or human/animal tissue require approval from an Institutional Review Board (IRB) or Scientific Review Committee (SRC) **before** experimentation begins (see Item #9, Form 1A).
3) Each student or team must submit a (maximum) 250-word, one-page abstract which summarizes this year's work. The abstract must describe research conducted by the student, not by adult supervisors (see *Student Handbook*).
4) Each student should display a project data book and a research paper (see *Student Handbook*).
5) All signed forms, certifications, and permits must be available for review at each fair a student enters. We recommend these be kept in a notebook or folder.
6) Any proposed changes in the research plan by the student after initial IRB/SRC approval must have subsequent IRB/SRC approval before experimentation begins/resumes.
7) Projects which are continuations of previous year's work and which require IRB/SRC approval must be reapproved prior to experimentation for the current year.

Limitations

1) Each student may enter only **one** project.
2) Team projects may have a maximum of three members (see below).
3) ISEF exhibits must adhere to ISEF safety and size requirements (see page 6).
4) Students may compete in only **one** ISEF affiliated fair, except when proceeding on to a state fair affiliated with the ISEF from an affiliated regional fair.

Continuation of Projects

Students will be judged only on research completed since the last ISEF. Display boards should reflect the current year's work only. However, supporting data books (not research papers) from previous related research may be exhibited with the project. Any continuing research must document substantial expansion of experimentation. Documentation must include the prior year's abstract and forms that were approved by an SRC. Copies with appropriate signatures must be attached, in sequence, behind the current year's research plan and forms. Each page of prior work must be clearly labeled in the upper right hand corner with the year involved (ex: 1994-95).

Team Projects

Team Projects compete against each other in a 14th Category that includes research in any scientific discipline. An affiliated fair has the option of sending a team project, in addition to two individual projects, to the ISEF. Team Projects are not required but are encouraged. Teams may have up to three members. NOTE: Teams may not have more than three members at a local fair and then eliminate members to qualify for the ISEF. A Team Project cannot be converted to an individual project. A new member may not be added to a continuing Team Project, but two original team members may continue their research if the third member no longer participates.

Each team should appoint a team leader to coordinate the work and act as spokesperson. However, each member of the team should be able to serve as spokesperson, be fully involved with the project, and be familiar with all aspects of the project. The final work should reflect the coordinated efforts of all team members and will be evaluated using the same rules and similar judging criteria as the other 13 categories (see *Student Handbook*, Judging). Each team member must submit individual 1A and 1B forms. The team members must jointly submit one abstract and one research plan that outlines each person's tasks, as well as other required forms. Names of all team members must appear on the abstract and forms.

Who Is Involved in a Science Project?

1) The Adult Sponsor

An adult sponsor may be a teacher, parent, university professor, or scientist in whose lab the student is working. This individual must have a solid background in science and should have close contact with the student during the course of the project.

The Adult Sponsor is ultimately responsible not only for the health and safety of the student conducting the research, but also for the humans or animals used as subjects. The Adult Sponsor must review the student's research plan to make sure that a) experimentation is done within local, federal, and these Science Fair/ISEF Rules, and b) that forms are completed by other adults involved in approving or supervising any part of the experiment.

The Adult Sponsor must be familiar with the regulations that govern potentially dangerous research as they apply to a specific student project. These may include chemical and equipment usage, experimental techniques, research involving human or nonhuman animals, and cell cultures, microorganisms, or animal tissues. The issues must be discussed with the student when drafting the research plan. Some experiments involve procedures or materials that are regulated by state and federal laws. If not thoroughly familiar with the regulation, the Adult Sponsor should help the student enlist the aid of a Qualified Scientist.

The Adult Sponsor is responsible for making the student's research eligible for entry in the International Science and Engineering Fair.

2) The Qualified Scientist

A Qualified Scientist should possess an earned doctoral/professional degree in the biomedical sciences. However, a master's degree with equivalent experience and/or expertise is acceptable when approved by a Scientific Review Committee (SRC). The Qualified Scientist must be thoroughly familiar with the local, state, and federal regulations that govern the student's area of research.

The Qualified Scientist and the Adult Sponsor may be the same person, if that person is qualified as outlined above.

A student may work with a Qualified Scientist in another city or state. In this case, the student must work with a Designated Supervisor (see below) who has been trained in the techniques the student will use.

3) The Designated Supervisor

The Designated Supervisor is an adult who supervises a student's experiment if the Qualified Scientist is unable to do so. In the case of hazardous substances or devices, a Designated Supervisor may be selected to be directly responsible for overseeing student experimentation, even though a Qualified Scientist may not be necessary. The Designated Supervisor need not have an advanced degree, but should be thoroughly familiar with the student's project, and must be trained in the student's area of research. The Adult Sponsor may act as the Designated Supervisor.

If a student is experimenting with live vertebrates and the animals are in a situation where their behavior or habitat is influenced by humans, the Designated Supervisor must be knowledgeable about the humane care and handling of the animals. If the Designated Supervisor is not knowledgeable, the Adult Sponsor must ensure that the student enlists the help of an Animal Care Supervisor.

4) The Animal Care Supervisor

The Animal Care Supervisor must be familiar with the proper care and handling of research animals used in the project and is required for all nonhuman vertebrate animal projects. The Qualified Scientist or Designated Supervisor or animal care professional usually serves as the Animal Care Supervisor.

5) The Institutional Review Board (IRB)

An Institutional Review Board (IRB) is a committee that, according to federal law, must evaluate the potential physical or psychological risk of research involving human subjects. All proposed human research must be reviewed and approved by an IRB before experimentation begins. This includes any surveys or questionnaires to be used in a project.

An IRB at the school or affiliated fair level must consist of at least three members:

a) science teacher
b) school administrator
c) and one of the following: psychologist, psychiatrist, medical doctor, or registered nurse

Due to the federal regulations requiring local community involvement, an IRB should be established at the school level to deal with human research projects. If it is impossible to establish an IRB at each local school, the teacher/school should contact the Regional Fair Director for assistance in evaluating human research prior to experimentation.

Notes

(a) If the project is behavioral, a psychologist, psychiatrist, or individual with human behavioral training must serve on the IRB.

(b) For subjects under 18, student researchers obtain written informed consent from all subjects and their parent/guardian.

(c) A fourth member should always be available as a substitute, if needed.

(d) Neither the Adult Sponsor nor the Qualified Scientist who oversees a specific project is permitted to serve on the SRC or IRB reviewing that project. Consequently, neither the Adult Sponsor nor the Qualified Scientist may sign the SRC portion of (1B) Approval Form. This eliminates conflict of interest.

6) Affiliated Fair Scientific Review Committee (SRC)

The SRC consists of the following persons:

a) biomedical scientist (Ph.D., M.D., D.V.M., D.D.S., or D.O.)
b) science teacher
c) at least one other member

Notes

(1) If you live in a rural area and do not have access to a degreed biomedical scientist, you may enlist the services of someone from another area. You should send to that person the rules and necessary forms so he or she is familiar with the procedures.

(2) One of the above members must be familiar with proper animal care procedures when animal research is involved.

(3) Local SRCs may be formed to assist an affiliated SRC in reviewing and approving projects. The operation and composition of the local SRCs must fully comply with these Science Fair/ISEF Rules.

(4) Neither the Adult Sponsor nor the Qualified Scientist who oversees a specific project is permitted to serve on the SRC or IRB reviewing that project. Consequently, neither the Adult Sponsor nor the Qualified Scientist may sign the SRC portion of (1B) Approval Form. This eliminates conflict of interest.

A Scientific Review Committee (SRC) examines projects for the following:

a) evidence of library search
b) type and amount of supervision
c) use of accepted research techniques
d) completed forms and signatures
e) humane treatment of animals
f) compliance with rules and laws governing human and animal research
g) appropriate use of recombinant DNA, pathogenic organisms, and controlled substances

The **SRC** follows a three-step process:

1) **BEFORE EXPERIMENTATION**, the SRC reviews and approves experimental procedures for projects involving human subjects, nonhuman vertebrates, pathogenic agents, controlled substances, recombinant DNA, and human/animal tissue to make sure they comply with the Rules and any pertinent laws. Human studies reviewed and approved by a properly constituted IRB do not have to be reviewed by the SRC until regional competition.
2) **AFTER EXPERIMENTATION AND SHORTLY BEFORE THE REGIONAL FAIR**, the SRC reviews and approves those same projects to make sure that students followed the approved Research Plan and the Rules.
3) **AFTER EXPERIMENTATION AND SHORTLY BEFORE THE REGIONAL FAIR**, the SRC also reviews all remaining projects to make sure students followed the Rules.

7) The ISEF Scientific Review Committee (ISEF SRC)

A Scientific Review Committee exists at the ISEF level as well. The ISEF SRC reviews the forms and research plans for all projects.

The ISEF SRC, like a regional SRC, is made up of a group of adults knowledgeable about regulations concerning experimentation in restricted areas. The ISEF SRC reviews and approves (1A) Research Plan and (1B) Approval Form in addition to all other required forms for students who enter the ISEF. They also identify problems local fairs may be having and work with fair directors and teachers to resolve them.

If a Fair Director or regional/local SRC member has any questions concerning the process, feel free to contact Science Service or a member of the ISEF SRC. (See p. 2 for phone numbers.) The ISEF SRC is the final authority on projects that are eligible to compete in the ISEF. In some cases, the ISEF SRC may have questions about particular projects. Usually, after students explain their procedures and research to the ISEF SRC, a simple corrective measure is prescribed (*e.g.*, contacting the Designated Supervisor to confirm a detail, or rewriting an abstract for purposes of clarification).

It is important that students retain signed copies of <u>all</u> paperwork. Even though copies may have been sent with registration papers, students should bring signed copies to ISEF in case an SRC interview is necessary.

Human Subjects

An Institutional Review Board (IRB) must review and approve all research involving human subjects **before** experimentation begins. The Science Fair/ISEF Rules, which follow federal regulations, exist to safeguard the rights and welfare of individuals who participate as research subjects. When students conduct biomedical or behavioral research, they are directly responsible for protecting the rights and welfare of the participating human subjects.

Rules

1) According to federal regulations, certain areas of human research are exempt from IRB review. However, the Science Fair/ISEF Rules do not permit these exemptions. **All human research projects (including surveys, professional tests, questionnaires, and studies in which the researcher is the subject of his/her own research) are subject to a complete IRB review before experimentation begins.** Copies of standardized tests and student-prepared tests, surveys, etc., must be included with the research plan.

2) Student researchers must assess the risks to their human subjects when developing research plans. Any risks must be described in **(4A) Human Subjects Form** for review and approval by an IRB before experimentation is started.

3) Precollege student research conducted at federally registered research institutions (*e.g.*, university labs, medical centers, NIH, etc.) must be reviewed and approved by that institution's IRB.

4) If the IRB requires any research plan changes, the student must incorporate those changes into the research plan **before the IRB signs for approval.**

5) Any proposed changes in the research plan by the student after initial IRB/SRC approval **must have subsequent IRB/SRC approval before such changes are made and before experimentation begins/resumes.**

6) After an IRB has approved the research proposal, the student may begin experimentation. Additional review by a local SRC is not required before experimentation.

7) A student may observe and collect data for analysis of new procedures and medications only under the direct supervision of a licensed professional. Students are prohibited from administering medications to human subjects. The IRB must ascertain that the student is not violating the medical practice act of that particular state or nation.

8) It is illegal to publish information in a report that identifies the human subjects directly or through identifiers linked to the subjects, including photographs. Names or photographs of human subjects may not be displayed with a project without informed consent. (Public Health Service Act, 42 U.S.C., 241(d).)

Notes on the Institutional Review Board (IRB)

1) Institutional Review Boards (IRBs) exist at federally registered research institutions. For research not performed at one of these facilities, the sponsoring research organization (high school, local or affiliated fair, etc.) must appoint an IRB to review and approve any proposed research involving human subjects.

2) A minimum of three members are required for a school or affiliated fair IRB. An IRB must include a science teacher, a school administrator, and one of the following: a medical doctor, registered nurse, psychologist, or psychiatrist. When the project concerns behavioral research, the IRB must include a psychologist or psychiatrist. (Federal law 25-CFR-46.)

3) An IRB generally makes the final determination of risk. However, if an SRC judges an IRB's decision as inappropriate, thereby placing human subjects in jeopardy, the SRC may override the IRB's decision.

Choosing a Study Group & Assessing Risks

When choosing a study group, the criteria for selecting the subjects should be clearly defined. In other words, students should ask questions that will define the exact study population. For example, if students want to study nondiabetic males, they should make sure to ask the appropriate questions that would eliminate diabetic individuals. Similarly, in studies where exercise is involved in the project, the student researcher should determine that the research subject is not at risk by exercising, e.g., the subject has no cardiac disease/disorder.

Once a population is chosen, the ISEF Rules require students to assess any potential risks when developing research plans. Any possible risks must be explained on **(4A) Human Subjects Form**. The student must submit **(4A) Human Subjects Form** with **(1A) Research Plan/(1B) Approval Form** to an IRB for review and approval before the beginning of experimentation.

Parents have the right to deny participation in any study including those involving tests or questionnaires. Certain surveys or questionnaires may be judged to involve risk by the IRB and informed consent (4B) may be required. Such questionnaires must be provided to parents with consent forms when requested.

In evaluating risk, students should use the following federal definition of minimal risk as a guide:

When the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during performance of routine physical or psychological examinations or tests.

The following are examples of activities or groups that **may** contain risks:

Activities

1) **Exercise**
2) **Emotional stress** resulting from invasion of privacy (See Privacy Act of 1974 45CFR5B). Questions on sexual activities or preferences, AIDS testing and results, suicide attitudes, divorce and its effects on psychological well-being all may be judged as overtly invasive or high-risk. Student researchers should always carefully evaluate controversial questions for compliance with federal regulations. Photographs that physically identify individuals are illegal without informed consent.
3) **Ingestion of any substance** or physical contact with any potentially hazardous materials. This rule applies to the student researcher as well as the human subject(s).

Groups

1) Any member of a group that is naturally at-risk (*e.g.*, pregnant women, individuals with diseases such as cancer, asthma, diabetes, cardiac disorders, psychiatric disorders, dyslexia, AIDS, etc.).
2) Special vulnerable groups covered by federal regulations (*e.g.*, children, prisoners, pregnant women, handicapped or mentally disabled persons, economically or educationally disadvantaged persons). Additional safeguards are applied to these subjects because they have been judged as vulnerable to coercion or undue influence.

Sources of Information

1) CFR, Title 45 (Public Welfare), Part 46-Protection of Human Subjects (45CFR46)
2) CFR, Title 45 (Public Welfare), Part 5b-Privacy Act Regulations (45CFR5b)
3) Public Health Service Act 42 U.S.C. S 241(d)
   (*Protection of Privacy of Individuals who are Research Subjects*)

Above documents available from:
Office for Protection from Research Risks
National Institutes of Health
Building 31, Room 5B63
9000 Rockville Pike, Bethesda, MD 20892
(301) 496-7005

Required Forms

A) **(1A) Research Plan/**
(1B) Approval Form
Must be submitted to an Institutional Review Board (IRB) for review and approval before student begins experimentation. A copy of any tests or questionnaires must be included with the research plan.

B) **(4A) Human Subjects Form**
Must be submitted to an IRB for review and approval before experimentation is started.

C) **(4B) Informed Consent Form**
This form is strongly recommended for all projects using human subjects and is required for all projects with acceptable risk. A sample of this form must be submitted to the IRB before experimentation begins.

If risks are determined to be present by the IRB, the following additional forms are required:

D) **(2) Qualified Scientist Form**
Required if any risk to the subjects is determined. Should the student anticipate that risk might be involved, this form must be provided to the IRB together with Form (1A)/(1B) and Form (4A) above at the time of original review by an IRB.

E) **(3) Designated Supervisor Form**
If the Qualified Scientist is unable to supervise the experiment, a Designated Supervisor who is knowledgeable about the project and its risks must supervise. This individual must have training in the procedures and methods used by the student to achieve the specific aims of the project.

F) **(4B) Informed Consent Form**
This form is required for all projects involving risk.

Note

If work was conducted in an institutional or industrial setting any time during the current ISEF project year, Form (1C) must be completed.

Nonhuman Vertebrate Animals

Students proposing research on nonhuman vertebrate animals should explore all possible alternatives. If vertebrates are used for research and testing, the student researchers and Adult Sponsors are responsible for granting the animals every humane consideration for their comfort and well being before, during, and after the research. Alternatives may include replacement, reduction or refinement.

The three Rs of animal experimentation:
Replace vertebrate animals with invertebrates or lower life whenever possible.
Reduce the number of animals whenever possible. (Do not reduce numbers beyond statistical validity.)
Refine experimental protocols to lessen pain or distress to the animals.

Rules

NOTE

Although certain research is permissible for professionals in research institutions, it may not be appropriate for high school students. Please review the limitations below.

1) **Alternatives**: Alternatives to the use of non-human vertebrate animals for research must be explored. We encourage any nonintrusive studies (*i.e.*, observational, behavioral, and natural history studies) that do not affect an animal's health or well-being by causing stress or discomfort. The Science Fair/ISEF Rules allow intrusive studies on vertebrate animals and invertebrate animals that have advanced nervous systems only when lower vertebrates or other alternatives are not suitable.

   Examples of possible alternatives are listed below:

   a) Cells and tissue cultures
   b) Plants (including lower plants such as yeast and fungi)
   c) Mathematical or computer models
   d) Invertebrates with either no nervous systems or primitive ones (*i.e.*, protozoa, planaria, insects)
   e) Primary tissue or cell explants from humanely euthanatized animals
   f) Chicken embryos prior to three days of hatching

2) The ISEF defines an animal as any live, nonhuman vertebrate, mammalian embryo or fetus, bird eggs within three days of hatching, and all other vertebrates at hatching or birth.

3) Students performing animal research must follow local, state, and federal regulations. Research conducted at registered research institutions (*e.g.*, university lab, medical center, NIH, etc.) must be reviewed and approved by that institution's Animal Care and Use Committee. Research conducted at all other sites must have prior SRC review and approval.

4) **Procurement**: All animals must be legally acquired from reputable animal breeders.

   a) Common laboratory animals must be obtained from licensed laboratory animal breeders. Pet store animals, except fish, are inappropriate because their genetic and nutritional background and disease status are unknown. Fish may be obtained locally.

   b) Animals should be healthy and free of diseases that can be transmitted to humans or other animals.

   c) Animals may not be captured from or released into the wild without approval of responsible wildlife and public health officials.

   d) All animals are classified as laboratory animals on the first day of study. Proper forms must be completed and approved by the SRC before experimentation is started.

5) **Housing**: The ISEF accepts two basic animal care guides on the care and use of laboratory animals: *Federal Animal Welfare Act*, and the *Guide for the Care and Use of Laboratory Animals*. For farm animals, use the *Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching* (*Agri-Guide*). Any deviations from these guides must be approved by an Animal Care Supervisor and the governing SRC.

   a) Animals must be housed in clean, ventilated, comfortable environments compatible with the standards and requirements appropriate for the species used. Animals must have adequate lighting, humidity and controlled temperature (with as little variation as possible), and have sanitizable cages of adequate sizes for the typical activities and social interactions of the species (unless individual housing is dictated by experimental protocol).

   b) Because the conditions above are critical, experiments involving small common laboratory animals (*e.g.*, mice, rats, hamsters, guinea pigs, gerbils, rabbits) are allowed in an **institutional setting** or **school setting** (if environment, housing and husbandry standards are maintained) and **not** in a student's home environment. Home environments are not as tightly controlled as institutional settings and therefore are not appropriate for

experimentation. Exceptions for behavioral and agricultural research may be granted by the governing SRC.

6) **Husbandry**: Animals should be treated kindly and cared for properly.

   a) Animals must be given a continuous, clean (uncontaminated) water and food supply. Food should meet the nutritional requirements of the particular species. Standard laboratory formulations should always be used for common laboratory animals (unless prevented by experimental protocol). Watering and feeding devices should be cleaned frequently.

   b) Proper care must be provided at all times including weekends, holidays, and vacation periods. Animals must be observed daily to assess their health and well-being.

   c) Cages, pens, and fish tanks must be cleaned frequently. A highly absorbent bedding should be used in cages and pens. Hardwood (not cedar) chips are recommended and can be obtained from local pet or feed stores. Do not use newspaper or paper towels because inks may be carcinogens and adversely affect liver enzyme function.

   d) If an unexpected illness or emergency occurs, animals must have proper veterinary medical and nursing care.

7) Research on animals involving anesthetics, drugs, thermal procedures, physical stress, organisms pathogenic for humans or other vertebrates, ionizing radiation, carcinogens, tumors, or surgical procedures must be directly supervised by a Qualified Scientist or Designated Supervisor within a hospital, school, or clinical/research institution approved by the governing SRC. **Students are prohibited from doing such research in a home environment, even if institutional housing is not available.**

8) Experimental procedures that cause unnecessary pain or discomfort **may not be attempted** on any vertebrate animals (*e.g.*, mammals, birds, reptiles, amphibians, fish).

9) Research in nutritional deficiency, ingestion, inoculation or exposure to hazardous or reputedly toxic materials or drugs is permitted to proceed only to the point where signs or lesions of the deficiency or toxicity appear. Appropriate measures must then be taken to correct the deficiency, toxicity, or drug effect, if such action is feasible. If not, the animal(s) must be euthanatized. **Experiments designed to kill vertebrate animals are not permitted. However, experimental designs incorporating humane euthanasia are permitted.**

10) Stress research is permitted only when it causes no permanent alteration in the psychological or physical well-being of the animals.

11) Proper euthanasia at the end of experimentation for tissue removal and/or pathological analysis is permitted.

   a) **Acceptable Methods of Euthanasia**: administration of barbituric acid derivatives in conformance with applicable laws; inhalation of gas anesthetic in a well ventilated area; induced narcosis with carbon dioxide or nitrogen for common laboratory animals; use of MS-222 or a combination of hypothermia and CO_2 narcosis for aquatic species.

   b) **Unacceptable Methods of Euthanasia**: injection of air, or any product containing strychnine, curare, succinylcholine or other neuromuscular blocking agents; guillotine, decapitation and cervical dislocation without prior anesthesia; exhaust fumes; chloroform or ether; stunning blows to the head; microwaves. These methods are unacceptable for student research projects regardless of who conducts the procedure.

12) Only the Animal Care Supervisor, Qualified Scientist, or the Designated Supervisor may perform euthanasia. **Student researchers may perform euthanasia only in an emergency.**

13) LD means **lethal dose** or death rate. **A death rate of 50 percent or greater in any group or subgroup, by design or as an unexpected result of experimental procedure, is not permitted.**

14) Weight loss is one significant sign of stress or toxicity. Maximum permissible weight loss or growth retardation (compared to controls) of any experimental or control animal(s) is 15 percent.

15) Acid rain, insecticide, herbicide, and heavy metal toxicity studies or behavioral studies using low toxicity on live vertebrates are prohibited. Tissue culture, chicken embryos up to three days before hatching, and invertebrate studies are recommended as alternative models for testing.

Required Forms

Note

If your project is a continuation from previous year(s), attach copies of all signed forms from said year(s) to the current year's research plan and forms.

A) **(1A) Research Plan/**
(1B) Approval Form
Must be submitted along with the following forms to a Scientific Review Committee (SRC) for review and approval before student begins experimentation.

B) **(2) Qualified Scientist Form**
Required for any project involving nonhuman vertebrate animals.

C) **(3) Designated Supervisor Form**
If the Qualified Scientist is unable to directly supervise the experiment, a Designated Supervisor who has thorough knowledge of the student's research project must supervise. The Designated Supervisor need not have an advanced degree, but must have training in the standards of nonhuman vertebrate animal research.

D) **(5) Nonhuman Vertebrate Animal Form**
Students must enlist an adult who is knowledgeable about animal care to oversee the care and handling of animals. The Animal Care Supervisor must sign this form. If multiple vertebrate animal species are used in a project, a separate Nonhuman Vertebrate Animal Form must be completed for each species.

Note

If work was conducted in an institutional or industrial setting anytime during the current ISEF project year, Form (1C) must be completed.

Special Note About (1A) Research Plan

Question #11 on the (1A) Research Plan asks for a description of methods and procedures. Projects that involve vertebrate animals require an extremely detailed research plan for SRC review purposes. Although most of the following information is requested on (5) Nonhuman Vertebrate Animal Form, the SRC requires a comprehensive plan detailing the specifics listed below:

1) Describe in detail, how the animals will be used. Include methods and procedures, such as experimental design and data analysis. Identify the specie, strain, sex, age, weight, source and number of animals proposed for use.

2)Justify why animals must be used, including the reasons for the choice of species and the number of animals to be used. Describe any alternatives to animal use that were considered, and the reasons these alternatives were unacceptable. Explain the potential impact or contribution this research may have on the broad fields of biology or medicine.

3) Provide detailed information on the animal's housing, husbandry, and environment. Also, provide information on the veterinary medical/nursing care, to be obtained in the case of illness or emergency.

4) Describe the procedures that will limit any unavoidable discomfort, distress, pain and injury to the animals during the course of experimentation. Redundant work or experiments which duplicate previous research by others should be avoided.

NOTE

The ISEF discourages any procedures that will cause discomfort to animals.

5) Describe any analgesic, anesthetic or tranquilizing drugs (show dosage in **mg/kg of bodyweight**) and comfortable restraining devices used to minimize discomfort, distress, pain, and injury. Also indicate dosage of any drugs or substances used in the animals in mg/kg of body weight.

Calculation of Dosage: If one doses a 20 gram mouse with 40 mg of saccharin (using Sweet-n-Low), how many mg/kg (of bodyweight) is this dosage? **Note: A one-gram (1,000 mg) packet of Sweet-n-Low contains only 40 mg of active ingredient saccharin.** The rest of the packet contains inert ingredient(s). This condition is true for many foods and pharmaceutical products.

Step 1: Establish the weight of the variables. In this example, the mouse weighs 20 g and the saccharin dosage is 40 mg.

Step 2: Convert the weight of the mouse into kg.

$$1\text{ kg} = 1{,}000\text{ g};\ \frac{20\text{ g}}{1{,}000\text{ g}} = 0.02\text{ kg}$$

Step 3: Compute the ratio between the weight of saccharin to the weight of the mouse using the following formula:

$$\text{dosage} = \frac{\text{weight of saccharin (mg)}}{\text{weight of mouse (kg)}}$$

$$\text{Thus, dosage} = \frac{40\text{ mg}}{0.02\text{ kg}} = 2{,}000\text{ mg/kg}$$

6) Explain what will happen to the animal(s) after the project is finished. If euthanasia will be performed by a Qualified Scientist (**students are not permitted to perform euthanasia except in an emergency**), describe the method and reasons for selection. Methods should comply with the Euthanasia Guidelines in the 1993 AVMA report.

Sources of Information for Animal Care and Use

1) *Guide for the Care and Use of Laboratory Animals* (The *Guide*, NIH Publication 85-23)

Office for Protection fr. Research Risks (OPRR)
National Institutes of Health
9000 Rockville Pike, Building 31, Room 5B63
Bethesda, MD 20892
(301) 496-7163

2) Federal Animal Welfare Act (*AWA*)
7 U.S.C. 2131-2157
Sub-chapter A - Animal Welfare (Parts I, II, III)

Regulatory Enforcement & Animal Care
U.S. Department of Agriculture
6505 Belcrest Road, Room 565, Federal Building
Hyattsville, MD 20782
(301) 436-7833

3) *Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching (Agri-Guide)*

American Dairy Science Association
309 West Clark Street
Champagne, IL 61820
(217) 356-3182

Sources of Information for Alternative Research and Animal Welfare

1) The National Library of Medicine provides computer searches through MEDLINE under the key phrase Animal Welfare.
Reference Librarian
National Library of Medicine
8600 Rockville Pike
Bethesda, MD 20894
(301) 496-6097 or
(800) 272-4787

2) National Agriculture Library (NAL) provides reference service for materials that document a) Alternative Procedures to Animal Use and b) Animal Welfare.
Animal Welfare Information Center
National Agriculture Library
5th Floor, 10301 Baltimore Blvd.
Beltsville, MD 20705
(301) 504-5215

3) Institute of Laboratory Animal Resources (ILAR) provides a variety of information on animal sources, housing and handling standards, and alternatives to animal use through annotated bibliographies published quarterly in *ILAR News*.

Dr. Thomas L. Wolfle, Program Director
Institute of Laboratory Animal Resources
National Research Council
National Academy of Sciences
2101 Constitution Avenue, N.W.
Washington, DC 20418
(202) 334-2590

Quarterly bibliographies of Alternatives may be obtained from:

Dr. Sid Siegel, Chief, OSHI
8600 Rockville Pike, Building 38A, Room S-404
Bethesda, MD 20894
(301) 496-5022

4) Euthanasia Guidelines

1993 Report of the AVMA Panel on Euthanasia published in the *Journal of the American Veterinary Medical Association* (JAVMA), Vol. 203, No. 2: 229-249, 1993.

Other Federal Laws that May Apply

1) Marine Mammal Conservation and Protection Act (16 U.S.C. 1361)

Office of Public Affairs
National Oceanic & Atmospheric Admin.
1315 East-West Highway, Rm. 14400
Silver Spring, MD 20910
(301) 713-2370

2) Endangered Species Acts (16 U.S.C. 1531)

Department of the Interior
Publications Service
4401 N. Fairfax Drive
Arlington, VA 22203
(703) 358-1711

Other Guidelines and Regulations that May Apply to Animal Research Projects or Laboratory Safety

1) Carcinogens, Chemicals and r-DNA

National Institutes of Health
Division of Safety
Building 31, Room 1C02
Bethesda, MD 20892
(301) 496-1357

2) Infectious Agents

Centers for Disease Control
Office of Biosafety
1600 Clifton Road F-05
Atlanta, GA 30333
(404) 639-3235

3) Isotopes

Larry Camper
U.S. Nuclear Regulatory Commission
Medical & Academic Use
TFWN
11555 Rockville Pike
Rockville, MD 20855
(301) 415-7269

4) Radiation and Medical Devices

Food and Drug Administration
Center for Devices and Radiological Health
Office of Compliance, HFZ-300
2098 Gaither Road
Rockville, MD 20850
(301) 594-4692

5) Safety and Health

Delbert Flowers, Director
Office of Academic & Professional Affairs
Department of Labor
Occupational Safety and Health Administration
200 Constitution Avenue, N.W.
Washington, DC 20210
(202) 219-8021

Pathogenic Agents

The Science Fair/ISEF allow students to experiment with pathogenic agents as long as the students adhere to federal regulations and guidelines, which are designed to protect the safety of researchers. Carelessness and improper techniques in working with pathogenic agents can lead to laboratory- and/or field-contracted infections.

Rules

1) Pathogenic agents are disease-causing or potentially disease-causing agents such as bacteria, viruses, rickettsia, fungi, or parasites. When using pathogenic agents, student researchers and their Adult Sponsors are required to follow standard microbiological practices, as defined in *Biosafety in Microbiological and Biomedical Laboratories*. Such organisms collected, isolated, and/or cultured from any environment during student research projects, should be considered as potentially pathogenic. Purchased strains should be identified with full name, source and number in **(1A) Research Plan.**

2) Student research with pathogenic agents may be performed only under the direct supervision of an experienced Qualified Scientist or Designated Supervisor in an institutional laboratory, including a school if facilities are adequate and appropriate.

3) **Any proposed changes in the research plan by the student after initial SRC approval must have subsequent SRC approval before such changes are made and before experimentation begins/resumes.**

Required Forms

A) **(1A) Research Plan/(1B) Approval Form**
Must be submitted along with the form(s) below to a Scientific Review Committee (SRC) for review and approval before student begins experimentation.

B) **(2) Qualified Scientist Form**
Students using pathogens must enlist the expertise of a Qualified Scientist to oversee their projects.

C) **(3) Designated Supervisor Form**
If a Qualified Scientist is unable to supervise the student's experiment, a Designated Supervisor who is trained and thoroughly knowledgeable about the student's research project must supervise. The Designated Supervisor need not have an advanced degree, but must have training in the standards of good microbiological practices and a working knowledge of the organisms.

NOTE

If work was conducted at an institutional or industrial setting at any time during the current ISEF project year, Form (1C) must be completed.

Sources of Information

CDC-NIH Biosafety in Microbiological and Biomedical Laboratories
Publication #017-040-00523-7
Superintendent of Documents
U.S. Government Printing Office
Washington, DC 20402
(202) 783-3238

Controlled Substances

Controlled substances, including DEA classed substances, prescription drugs, alcohol, and tobacco, must be acquired and used according to existing local, state and federal laws.

Rules

1) Student researchers must adhere to all federal regulations governing controlled substances. For further information, contact the regulatory agencies listed above.

2) Production of alcohol is federally regulated and students must contact the Bureau of Alcohol, Tobacco and Firearms for regulations (see below).

3) Only under the direct supervision of a Qualified Scientist or Designated Supervisor may a student use any federally-controlled or experimental substances for therapy or experimentation. This includes over-the-counter drugs and potential new therapeutic substances.

4) Students under 21 years are prohibited by federal and most state laws from purchasing and/or handling smokeless powder or black powder. For further regulations, contact the Firearms & Explosives Division of the Bureau of Alcohol, Tobacco, and Firearms listed above.

Required Forms

A) **(1A) Research Plan/(1B) Approval Form**
Must be submitted with the form(s) below to a local or regional SRC for review and approval before experimentation is started.

B) **(2) Qualified Scientist Form**
Students using controlled substances must enlist the expertise of a Qualified Scientist to oversee their projects. The Qualified Scientist should have a thorough knowledge of the student's area of research.

C) **(3) Designated Supervisor Form**
If a Qualified Scientist is unable to supervise the student's experiment, a Designated Supervisor who is thoroughly knowledgeable about the student's research project may do so. The Designated Supervisor need not have an advanced degree, but must have training in working with controlled substances.

NOTE

If work was conducted in an institutional or industrial setting at anytime during the ISEF project year, Form (1C) must be completed.

Sources of Information

Prescription Drugs

Superintendent of Documents
U.S. GPO
Washington, DC 20402
(202) 783-3238

Alcohol, Tobacco and Firearms

The Bureau of Alcohol, Tobacco and Firearms
650 Massachusetts Ave., N.W.
Washington, DC 20226

Distilled Spirits and Tobacco Branch:
(202) 927-8210

Firearms & Explosives Division:
(202) 927-8300

Narcotics and Addictive Drugs

* The Drug Enforcement Administration
Registration Department
Washington, DC 20537
(202) 307-7255

*Contact appropriate state agencies concerning additional regulations.

Recombinant DNA (rDNA)

The Science Fairs/ISEF, following federal regulations, allow students to conduct recombinant DNA (rDNA) research. When using rDNA and host organisms, students and supervising adults are urged to proceed in a safe and responsible manner in the laboratory.

Rules

1) The ISEF adheres to NIH Guidelines and accepts the following definitions as recombinant DNA molecules:

    a) Molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell.

    b) Molecules that result from the replication of those described above.

2) Student researchers working with any microorganisms, whether or not they involve DNA, must always follow standard microbiological practices.

3) All student research proposals involving rDNA must be reviewed and approved by a Scientific Review Committee (SRC) before experimentation is started.

4) Students may conduct studies on both exempt and non-exempt rDNA and host organisms. (The ISEF Rules generally follow the NABT guidelines.)

    a) Non-exempt rDNA studies must be conducted in a federally registered research institution (*e.g.*, university lab, medical center, NIH, etc.) under the direct supervision of a Qualified Scientist. Copies of the institution's review and approval forms must accompany the required ISEF forms to the regional fair for the SRC to review after experimentation but before competition.

    b) Exempt rDNA studies may be conducted in non-federally registered laboratories, including school laboratories, under the direct supervision of a trained teacher, Qualified Scientist and/or Designated Supervisor must follow federal regulations.

        1) Exempt host organisms include the following: bacterium *Escherichia*, bacterium *Bacillus subtilus,* and yeast *Saccharomyces cerevesiae.*

        2) Exempt DNA insert molecules include the following: (a) DNA molecules that are not in the DNA of organisms or viruses, (b) DNA from single non-chromosomal or viral sources, and (c) DNA that is entirely from a prokaryotic host, including its indigenous plasmids or viruses when propagated only in the host.

        3) The following DNA molecules and host organisms are recommended: (a) DNA molecules: vectors (pAMP, pKAN, pUC, pBR322, M13), (b) host organisms: *E. coli* K-12 strains: MM 294, HB 101, JM 101, and (c) DNA inserts; *Bacteriophage lambda, Bacteriophage T4, E. coli* sequences, recombinants of any of the above listed plasmids.

    c) Important Restrictions:

        1) Recombinants containing DNA coding for oncogens or other human, plant or animal toxins (including viruses) cannot be made and/or propagated.

        2) Students must not use ethidium bromide or handle gels stained with ethidium bromide.

5) **Any proposed changes in the research plan by the student after initial SRC approval must have subsequent SRC approval before such changes are made and before experimentation begins/resumes.**

Required Forms

A) **(1A) Research Plan/(1B) Approval Form**
Must be submitted along with the forms below to a Scientific Review Committee (SRC) for review and approval before student begins experimentation.

B) **(2) Qualified Scientist Form**
Students using non exempt rDNA must enlist the expertise of a Qualified Scientist to oversee their projects.

C) **(3) Designated Supervisor Form**
If a Qualified Scientist is unable to supervise a student's non exempt rDNA experiment, a Designated Supervisor who is thoroughly knowledgeable about the student's research project may supervise. A trained teacher (Designated Supervisor) can directly supervise exempt rDNA experiments. The Designated Supervisor need not have an advanced degree, but must have training in the standards of good microbiological practices and a working knowledge of the organisms.

Note
If work was conducted in an institutional or industrial setting at anytime during the current ISEF project year, Form (1C) must be completed.

Sources of Information

NIH Guidelines for Research Involving Recombinant DNA Molecules

Office of Recombinant DNA Activities
National Institutes of Health
Building 31, Room 4B-11
Bethesda, MD 20892
(301) 496-9838

CDC-NIH Biosafety in Microbiological and Biomedical Laboratories

Publication #017-040-00523-7

Superintendent of Documents
U.S. Government Printing Office
Washington, DC 20402
(202) 783-3238

Working with DNA & Bacteria in Pre-College Science Classrooms

National Association of Biology Teachers
11250 Roger Bacon Drive #19
Reston, Virginia 22090
(703) 471-1134

Human and Animal Tissue

Research involving human or nonhuman vertebrate animal tissue must be approved by a Scientific Review Committee (SRC) before experimentation is started. For the purpose of student research, all body fluids, including saliva and urine, are to be considered tissue.

Rules

1) A **(6) Human and Animal Tissue Form** is required for all research projects using human or nonhuman vertebrate animal tissue when such tissue is obtained by the student from any research institution, biological supply house, or biomedical scientist.

2) Students may conduct research on human blood, blood products or other body fluids under either one of the following conditions: a) tissue fluids are documented free of HIV and hepatitis B and C before the student receive them; b) tissues are handled in accordance with standards and guidelines set forth in Occupational Safety and Health Act, 29CFR, Subpart Z, 1910.1030 - Blood Borne Pathogens.

3) Students using their own blood do not need the HIV or hepatitis certifications (see #2).

4) Several types of tissue are exempt, and do not require a (6) Human and Animal Tissue Form or prior SRC approval.

   a) Plant tissue
   * b) Established cell and tissue cultures (*e.g.*, those obtained from the American Type Culture Collection).
   c) Meat or meat by-products obtained from food stores, restaurants, or packing houses..

*Identify culture source and number in **(1A) Research Plan**.

Required Forms

A) **(1A) Research Plan/(1B) Approval Form**
Must be submitted to a local or regional SRC for review and approval before student begins experimentation.

B) **(6) Human and Animal Tissue Form**:
This form is not required for prior SRC review. However, an SRC must review this form prior to judging. Students should display this form with the project.

C) **(2) Qualified Scientist Form**
If non certified tissues or fluids are to be handled by the student.

Note
If work was conducted in an institutional or industrial setting at anytime during the current ISEF project year, Form (1C) must be completed.

Sources of Cultures

American Type Culture Collection
12301 Parklawn Dr.
Rockville, MD 20852
(301) 881-2600

Carolina Biological Supply Company
Main Office and Laboratories
2700 York Rd.
Burlington, NC 27215
(910) 584-0381 / (800) 334-5551

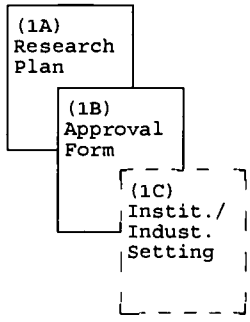
Forms

Flow Charts for Required Forms

Required

May Be Required

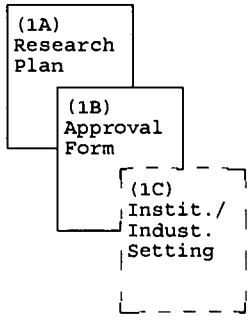
1) All Projects:



- Student completes **(1A) Research Plan** and **(1B) Approval Form**, and reviews with Adult Sponsor to determine if SRC/IRB approval is necessary before experimentation. *Every student must write an abstract for review by an SRC **prior to competition**.*

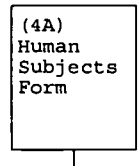
NOTE: If work was conducted at an institutional or industrial setting at any time during the current ISEF project year, Form (1C) must be completed.

2) Human Subjects:



- Student completes **(1A) Research Plan** and **(1B) Approval Form**, and reviews with Adult Sponsor prior to IRB Approval.

NOTE: If work was conducted at an institutional or industrial setting at any time during the current ISEF project year, Form (1C) must be completed.



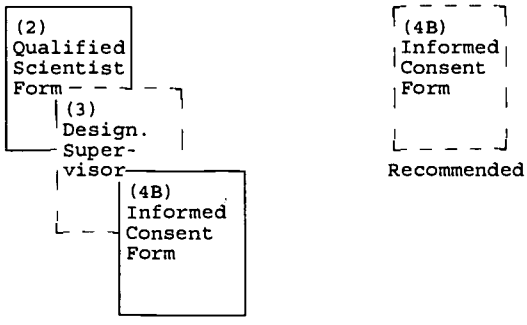
- Student completes **(4A) Human Subjects Form** and submits along with Forms (1A) and (1B) to an Institutional Review Board (IRB) for risk assessment and approval **before experimentation begins**.

IRB Decision
(acceptable risk involved)

IRB Decision
(no risk involved)

If IRB determines risks to be present:

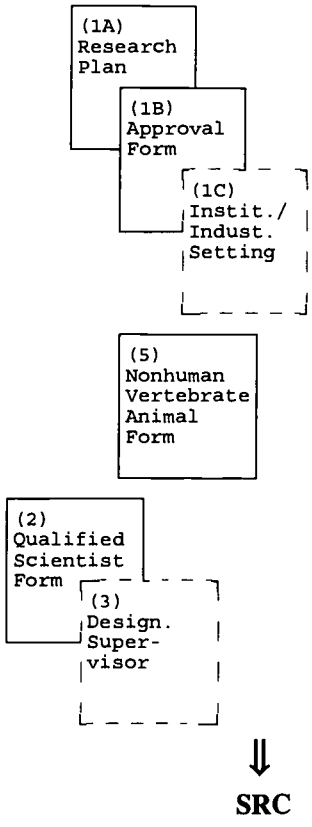
- Student enlists a Qualified Scientist to oversee the project and complete **(2) Qualified Scientist Form**. If Qualified Scientist cannot be present during experimentation, a Designated Supervisor must supervise and complete **(3) Designated Supervisor Form.** The student **must** obtain **(4B) Informed Consent Form** for each test subject.



If the IRB determines no risks,

- The student should obtain **(4B) Informed Consent Form** for each test subject.

3) Nonhuman Vertebrate Animals



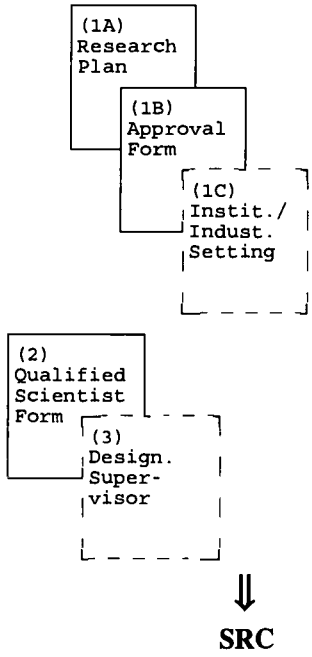
- Student completes **(1A) Research Plan** and **(1B) Approval Form**, and reviews with Adult Sponsor prior to SRC approval.

  NOTE: If work was conducted at an institutional or industrial setting at any time during the current ISEF project year, Form (1C) must be completed.

- Student completes **(5) Nonhuman Vertebrate Animal Form**. Animal Care Supervisor agrees to supervise the care and handling of the animals and signs the bottom section of **Form 5**.

- Student enlists a Qualified Scientist to oversee the project and complete **(2) Qualified Scientist Form**. If the Qualified Scientist cannot be present during experimentation, a Designated Supervisor must supervise and complete **(3) Designated Supervisor Form**.

4) Pathogenic Agents and Controlled Substances

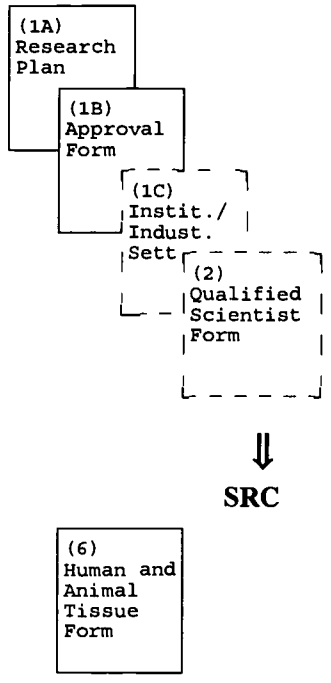


- Student completes **(1A) Research Plan** and **(1B) Approval Form**, and reviews with Adult Sponsor prior to SRC approval.

  NOTE: If work was conducted at an institutional or industrial setting at any time during the current ISEF project year, Form (1C) must be completed.

- Student enlists a Qualified Scientist to oversee the project and complete **(2) Qualified Scientist Form**. If the Qualified Scientist cannot be present during experimentation, a Designated Supervisor must supervise and complete **(3) Designated Supervisor Form**.

5) Human or Animal Tissue



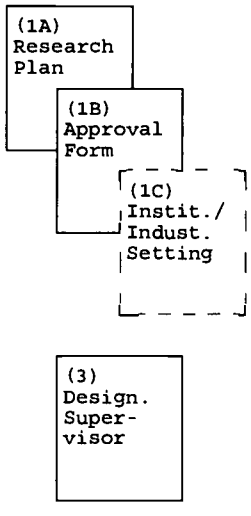
- Student completes **(1A) Research Plan** and **(1B) Approval Form**, and reviews with Adult Sponsor prior to SRC approval.

  NOTE: *If work was conducted at an institutional or industrial setting at any time during the current ISEF project year, Form (1C) must be completed.*

- **(2) Qualified Scientist Form** is required for studies if non-certified tissues are to be handled by the student.

- After SRC approval, student completes **(6) Human and Animal Tissue Form** and submits to regional/state/ISEF for review prior to competition.

6) Hazardous Substances or Devices

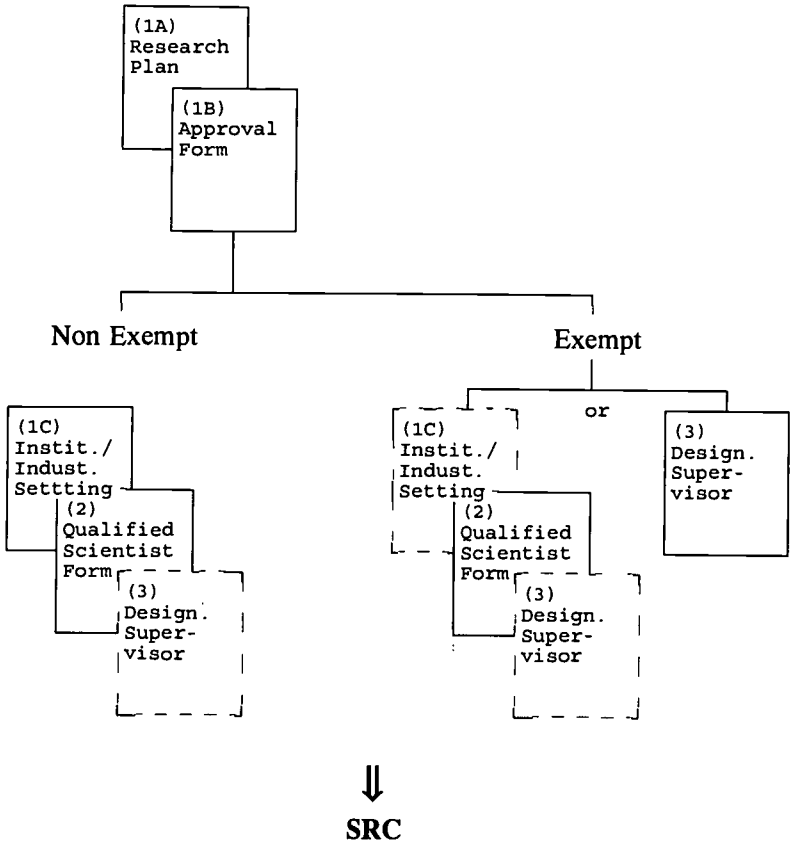


- Student completes **(1A) Research Plan** and **(1B) Approval Form**, and reviews with Adult Sponsor to determine if SRC/IRB approval is necessary before experimentation.

  NOTE: *If work was conducted at an institutional or industrial setting at any time during the current ISEF project year, Form (1C) must be completed.*

- Student enlists a Designated Supervisor to directly oversee the project and complete **(3) Designated Supervisor Form** (see p. 8).

7) Recombinant DNA:



- Student completes **(1A) Research Plan** and **(1B) Approval Form**, and reviews with Adult Sponsor prior to SRC approval.

- A determination is made regarding the nature of the rDNA.

  Non exempt rDNA studies must be conducted in a research institution and student enlists a Qualified Scientist to oversee the project. If the Qualified Scientist cannot be present during experimentation, a Designated Supervisor must supervise and complete **(3) Designated Supervisor Form.**

  Exempt rDNA studies must be supervised by a Qualified Scientist or Designated Supervisor. A trained teacher can be the Designated Supervisor.

Checklist for Adult Sponsor/Student Safety Assessment Form

Student Name _____

1) ☐ I have reviewed and signed the **(1A) Research Plan/(1B) Approval Form**.

2) ☐ The student and a parent/guardian have signed the **(1B) Approval Form**.

3) ☐ This project involves the following area(s) and requires prior approval before research begins:

☐ **Human Subjects**	☐ **Controlled Substances**
☐ **Nonhuman Vertebrate Animals**	☐ **Recombinant DNA**
☐ **Pathogenic Agents***	☐ **Human or Animal Tissue**

*All bacteria, fungi, etc. isolated from the environment should be considered potentially pathogenic.

Section 1: **Human Subjects**
If a project involves human subjects, the student has obtained approval from an **Institutional Review Board (IRB)** before experimentation is started. (See pp. 10-11.)

Section 2: **Nonhuman Vertebrate Animals, Pathogenic Agents, Controlled Substances, Recombinant DNA, Human/Animal Tissue**
If a project involves nonhuman vertebrate animals, pathogenic agents, controlled substances, recombinant DNA, or human/animal tissue, the student must have approval from a **Scientific Review Committee (SRC)** before experimentation is started. (See pp. 12-18.)

Section 3: **Hazardous substances or devices require review and proper supervision [(3) Designated Supervisor Form] but do not require prior approval.**

☐ **Chemicals** (*i.e.*, hazardous, flammable, explosive or highly toxic; carcinogens; mutagens, all pesticides). I have reviewed with the student the Material Safety Data Sheet (MSDS) Listing for each chemical that will be used. I have also reviewed the proper safety standards for each chemical including toxicity data, proper handling techniques, and disposal methods. For *Safety in the High School*, write to the American Chemical Society, Career Publications, 1155 16th St., NW, Washington, DC 20036 (202/872-6168).

☐ **Equipment** (*i.e.*, welders; lasers; voltage greater than 220 volts). I have reviewed with the student the proper operational procedures and safety precautions for the equipment to be used by the student. For information about laser standards and research, write to the Food and Drug Administration, Office of Compliance and Surveillance, 1390 Piccard Drive, Rockville, MD 20850 (301/427-1172).

☐ **Firearms.** I have reviewed with the student the proper safety standards for firearms use.

☐ **Radioactive Substances**. I have reviewed the proper safety standards for each radioactive substance the student will use.

☐ **Radiation** (*i.e.*, x-ray or nuclear; unshielded ionizing radiation of 100-400 nm wavelength). I have reviewed with the student the proper safety methods concerning the type of radiation the student will use.

_____ _____ _____
Adult Sponsor (print) (sign) Date

NOTE: This page should be part of the student's papers.

(1A) Research Plan

This completed form is required for ALL projects.

1) Student's Name _____ Grade _____
2) School, City & State _____
3) Title of Project _____
_____
4) Adult Sponsor _____
5) Is this a continuation from a previous year? ☐ Yes ☐ No If yes, see page 7 for instructions.
6) Proposed starting date of experimentation: __/__/__ (must be stated).
7) Where will you complete your lab work? ☐ Home ☐ School ☐ Research Institution ☐ Field
8) Name, address & phone of work site(s) _____ _____
Ex: Home _____ _____
202 State Street _____ _____
Anywhere, USA _____ _____
Phone

9) **Check all items that apply to your research:**

a) While doing my project, I will be experimenting with:

- ☐ **Humans** (requires prior IRB approval: complete Forms 1A,1B,4A [1C,2,3, 4B, if required])
- ☐ **Nonhuman Vertebrate Animals** (requires prior SRC approval: complete Forms 1A,1B,2,5 [1C,3, if required])
- ☐ **Recombinant DNA** (requires prior SRC approval: complete Forms 1A,1B,2 and/or 3 [1C, if required])
- ☐ **Pathogens** (requires prior SRC approval: complete Forms 1A,1B,2 [1C,3, if required])
- ☐ **Controlled Substances** (requires prior SRC approval: complete Forms 1A,1B,2 [1C,3, if required])
- ☐ **Human/Animal Tissue** (requires SRC approval: complete Forms 1A,1B,6 [1C and 2, if required])
- ☐ **Hazardous Substances or Devices** (complete Forms 1A,1B,3 [1C, if required])
- ☐ **None of the above** (complete Forms 1A,1B [1C, if required])

Type in the following spaces or attach a separate computer printout. Please limit to no more than three pages.

10) What is the problem, hypothesis or question you intend to investigate?

11) Describe in detail the method or procedures you intend to use.

12) Bibliography. List three (and only three) major sources (i.e., science journal articles, books) from your library research. If you plan to use animals, give an additional animal care reference.

(1B) Approval Form

This form is required for ALL projects.

1) Required for ALL projects.

a) **Student Approval:**

I understand the risks and possible dangers to me of the proposed Research Plan. I will adhere to all ISEF Rules when conducting this research.

Student's Signature _____ Date _____

b) **Parent/Guardian Approval:**

I have read and understand the risks and possible dangers involved in the Sponsor-approved Research Plan. I consent to my child participating in this research.

Parent/Guardian Signature (print & sign) _____ Date _____

c) **Adult Sponsor Approval:**

I have read the (1A) Research Plan prior to experimentation and reviewed the sponsor checklist on page 26 with the student. I agree to sponsor the student named above and assume reasonable responsibility for compliance with all ISEF and affiliated fair rules as they pertain to the Research Plan.

Adult Sponsor's Signature (print & sign) _____ Date _____

2) Required for those projects that need prior approval (i.e., see Item #10 on Form 1A.)

SRC Approval Before Experimentation

(IRB signs this for human projects.)

The Committee has carefully studied this research plan and all the required forms are included. My signature indicates approval of this research plan before the student begins experimentation.

SRC/IRB Chairperson's Signature (print & sign) _____ Date _____
Check one: ☐ Local or ☐ Affiliated Fair

3) Required for research conducted at research institutes when an SRC was not available.

SRC Approval After Experimentation

The Committee did not review and approve this research plan before experimentation. However, this project complies with ISEF Rules and was conducted at a registered research institution which reviewed and approved this project.

SRC Chairperson's Signature (print & sign) _____ Date _____
Check one: ☐ Local or ☐ Affiliated Fair

Note: If a stamp is used, it must be initialled by the chairperson.

4) Regional or State SRC Approval (required for ALL projects).

SRC Approval Before Competition at Regional/State Fair

I certify this project adheres to the approved Research Plan and complies with all rules of the Regional Fair and ISEF.

Regional SRC Chairperson's Signature (print & sign) _____ Date _____

State SRC Chairperson's Signature, where applicable (print & sign) _____ Date _____

(1C) Research Performed in an Institutional/Industrial Setting

This form must be completed by the scientist supervising the student research conducted in an institutional or industrial setting (e.g., university lab, medical center, NIH, SSTP, etc.)

This form MUST be displayed with your project.

Student's Name_____

Title of Project_____

To be completed by the Scientist:

The student conducted research at my institution: (check one)

a) ☐ only to use the equipment b) ☐ to perform experiment(s)

If b, the following questions must be answered:

1) How did the student get the idea for her/his project?
Was the project assigned, was it picked from a list of possible research topics, did it come out of discussion with a scientist, did it arise from some work in which the student was engaged, or did the student suggest it?

2) Did the student work on the project as part of a team or a group?
If yes, how large was the team, what kind of a team was it (students, group of adult researchers, etc.), and what was the student's role on the team?

3) How independently did the student work on the project?
What parts did the student do on her/his own, and what parts did she/he receive help with (the experimental design, choice of techniques, use of special instruments or equipment, construction of equipment, gathering data, evaluation of data, arriving at conclusions, etc.)?

4) What did the student do that showed creativity and ingenuity?
If you know of any examples, relate and indicate whether they were creative in terms of science.

5) Has the student received a salary or other compensation for doing her/his research?

6) Was this project reviewed and approved by your institution: ____ If yes, attach copy of approval.

Scientist's Signature (print) (sign) Title

Institution Date

Address Phone

(2) Qualified Scientist Form

Required for research involving animals, controlled substances and pathogens; may be required for rDNA, tissues, and humans. Must be signed prior to the start of student experimentation.

Student's Name_____

Title of Project_____

To be completed by the Qualified Scientist:

Scientist's Name_____

Earned Advanced Degree_____ Degree Specialty_____

Position_____

Institution_____

Address_____

Phone_____

1)	Will non-human vertebrate animals be used?	☐ yes	☐ no
2)	Will human subjects be used?	☐ yes	☐ no
3)	Will controlled substances be used? (includes DEA classed substances, prescription drugs, alcohol and tobacco)	☐ yes	☐ no
	If yes,		
	a) Will they be used according to existing local, state and federal regulations?	☐ yes	☐ no
	b) Please list the name(s) of the controlled substance(s):		
4)	Will recombinant DNA be used?	☐ yes	☐ no
5)	Will pathogenic agents be used?	☐ yes	☐ no
	If yes, name(s)_____		
	If yes, will accepted procedures be used?	☐ yes	☐ no
6)	Will human blood, blood products or body fluids be used?	☐ yes	☐ no

I certify that I have reviewed and approved the Research Plan prior to the start of the research. If the student or Designated Supervisor is not trained in the necessary procedures, I will ensure her/his training. I will provide advice and supervision during the research. I have a working knowledge of the techniques to be used by the student in this Research Plan. If an addictive substance is used in this research, I certify that I possess a DEA license required for procuring and dispensing an addictive substance. I understand that a Designated Supervisor is required when the student is not conducting research in my laboratory.

Qualified Scientist (print) _____ (sign) _____ Date _____

(3) Designated Supervisor Form

Required if the Qualified Scientist is unable to supervise the experiment or for certain projects using hazardous materials or devices.

Student's Name_____

Title of Project_____

To be completed by the Designated Supervisor (please print):

Name_____

Position_____

Institution_____

Address_____

_____

Phone_____

I certify that I have been trained in the techniques to be used by this student prior to the start of experimentation and that I will provide direct supervision.

Designated Supervisor (print) _____ (sign) _____ Date _____

(4A) Human Subjects Form

Required for all research involving humans.

Student's Name_____

Title of Project_____

To be completed by Student Researcher:
(All questions must be answered. If not applicable, explain why.)

1) Explain why human subjects are proposed or necessary for this research:

2) Describe and assess any potential risk (physical, psychological, social, legal or other):

3) Describe consent procedures to be followed (attach sample of completed form to be used):

4) Describe procedures to minimize risk:

5) Describe benefits to the individual or society:

6) Explain how the benefits exceed the risks:

To be completed by Institutional Review Board (IRB) prior to experimentation:
(Risk includes but is not limited to exercise, ingestion, physical and emotional stress, and invasion of privacy.)

☐ No risks involved: . . . . . Informed Consent (Form 4B) is strongly recommended for all human subjects.

☐ Acceptable risks involved: . . . . . Qualified Scientist and Informed Consent (Forms 2,4B) required.
Designated Supervisor (Form 3) may be required

☐ Unacceptable risks involved: Project must be revised.

		Specify position:		Chairperson (must identify; please circle one)
Member of IRB (print)	(sign)	Psychologist/Medical/Nurse (circle one)	Date	Yes No
Member of IRB (print)	(sign)	Science Teacher	Date	Yes No
Member of IRB (print)	(sign)	School Administrator	Date	Yes No

NOTES: **(1) The Adult Sponsor, Qualified Scientist, or Designated Supervisor cannot serve on the SRC/IRB for their particular project; (2) When project concerns behavioral research, the IRB must include a psychologist, psychiatrist or individual with human behavioral training; and (3) Tests or questionnaires of any type must be attached to the Research Plan and be reviewed by the IRB.**

(4B) Informed Consent Form*

Recommended for all projects involving human subjects; required for all projects involving risk.
***Use a separate form for each test subject.**

Student's Name_____ Grade_____
School, City & State_____
Title of Project_____

To be completed by Student Researcher:

1) What are the research procedures in which the subject will be involved?

2) What are the possible discomforts or risks that may reasonably be expected by participating in this research?

3) What procedures will be used to minimize the risks?

Qualified Scientist (print) (sign) Date
(If risk designated by the IRB)

Title Phone

Institution

Adult Sponsor (print) (sign) Phone

To be completed by human subject prior to experimentation:

☐ I have read and understand the conditions stated above, and I consent to participate in this research procedure. I realize that I am free to withdraw my consent and to withdraw from this activity at any time.

☐ I consent to use of visual images (e.g., photographs, videographs) involving my participation in this research project (optional).

Participant (print) (sign) Date

If participant is under 18 years old, a parent/guardian signature is required. If the subject of this experiment has any questions about this experiment, the Adult Sponsor should be contacted.

Parent's/Guardian (print) (sign) Date

Note: A copy of any test, survey, or questionnaire will be provided to you upon request.

(5) Nonhuman Vertebrate Animal Form

Required for all research involving nonhuman vertebrate animals.

NOTE: If nonhuman vertebrate tissue is used, this form is not necessary if the tissue was acquired by someone other than the student.

Student's Name_____

Title of Project_____

To be completed by Student Researcher:

1. Genus, specie, common name of animal(s) used _____
2. Where will animals be obtained? (Pet store animals not appropriate, except fish, which may be purchased locally.)
   _____
3. How many animals will be used?_____ Average Weight _____
4. Cage size_____ Number of animals per cage_____
5. Type of food_____
6. How often fed and given water?_____
7. Type of bedding used? (Do not use cedar chips, newspaper, or paper towels.)_____
8. Where will animals be housed?_____
9. Who will provide veterinary medical and nursing care in case of illness or emergency? Provide name of D.V.M.
   Name of D.V.M_____ Name of Facility_____
10. Will euthanasia of animals be necessary? ☐ Yes ☐ No
    If yes, by what method?_____ By whom?_____
    If no, what will happen to the animals after experimentation?_____
    _____

To be completed by Animal Care Supervisor or Qualified Scientist:

Name_____

Position_____

Institution_____

Address_____

Office Phone_____

I certify that I have discussed this research with the student prior to its start and will supervise and will accept primary responsibility for the quality of care and handling of the live vertebrate animals used by the above named student. I further certify that I am knowledgeable in the proper care and handling of laboratory animals, and meet prevailing animal care supervisory requirements. When an animal must be euthanatized, I certify that I will be present and will perform the procedure, using recommended agents.

_____ _____ _____

Animal Care Supervisor or Qualified Scientist (print) (sign) Date

_____ _____

Title Phone

_____

Institution and Address

(6) Human and Animal Tissue Form

Required for all projects using viable fresh tissue, organs, human or animal parts, including blood, blood products, teeth, cell cultures, and body fluids. (Plant tissue is excluded.)

Student's Name_____
Title of Project_____

To be completed by Student Researcher:

1) What were the tissue(s), organ(s), or part(s) used?

2) Human or animal material:

   a) Where was the above tissue, organ or part obtained: (identify each separately)

   b) If obtained from an animal source, why was the animal euthanatized?

To be completed by provider of tissue when obtained from a non-commercial source:

a) Human blood and blood products have been tested and documented free of AIDS and hepatitis B and C antibodies and antigens. Human teeth are certified free of blood and blood products.

Certifying Authority (print) _____ (sign) _____ Date _____

b) I certify that tissues and fluids are being handled in this project in accordance with the standards and guidence set forth in Occupational Safety and Health Act, 29CFR, Subpart Z, 1910.1030 - Blood Borne Pathogens.

Qualified Scientist (print) _____ (sign) _____ Date _____

I certify that the above listed materials were provided by me and that the student listed was not involved in the direct acquisition of the samples provided or purchased.

Print _____ Sign _____ Date _____

Title _____ Phone _____

Institution _____

SRC Chairperson (print) _____ (sign) _____ Date _____

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Signature: Yvonne D. Tilghman

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